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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,304	11/27/2001	Robert H. Kraus JR.	S-94,769	8960

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UNIVERSITY OF CALIFORNIA
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LOS ALAMOS, NM 87545

EXAMINER

DO, PENSEE T

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/995,304

Applicant(s)

KRAUS ET AL.

Examiner

Pensee T. Do

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) 17-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-63 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

5-05

DETAILED ACTION

Amendment Entry & Claim Status

The amendment filed on March 30, 2005 has been acknowledged and entered.

Claims 1-63 are pending. Claims 1-16 are being examined. Claims 17-63 are withdrawn from further consideration.

The claims being examined from hereon are based on the most recent filed claims. Since there is not much difference between the "elected claims" and the "original claims", the art rejections still apply.

Withdrawn Rejection(s)

Rejection under 112, 2nd paragraph in the previous office action is withdrawn herein.

Rejections under 102 by Wilson and Blankenstein are withdrawn herein.

Rejection under 103 by Wilson is also withdrawn herein.

Maintained Rejection(s)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Miltenyi (US 5,543,289).

Miltenyi teaches a process for conducting of high gradient magnetic separation (HGMS). Superior superparamagnetic particles, coated with a polymer such as a polysaccharide or polystyrene, can be prepared in uniform compositions with homogeneous magnetizations. The coating can be conjugated to specific binding moiety complementary to a biological material whose purification or separation is desired. Then magnetization of the particles is measured. Magnetization means the magnetic moment per volume of the magnetic particles. Identical magnetic field for all the particles in the mixture is imposed. The superparamagnetic particles range from 0.04 μm to 0.1 μm in size. (see claim 1). Target biological materials are proteins, cells, viruses, bacteria, yeasts, glycoproteins, etc. (see col. 9, lines 6-21). Any number of components in a biological mixture can be labeled with particles of differing magnetizations by treating each homogeneous composition of particles with a different specific binding moiety complementary to a chosen component of the mixture. Each component will then uniquely react with one representative composition of a particular magnetization. The labeled mixture, when subjected to HGMS results in a chromatographic pattern of components separated according to the magnetization of the particles with which they are conjugated. (see col. 11, lines 54-65). Miltenyi also teaches that the superparamagnetic particles can be subjected to HGMS at any stage of its preparation process-before or after coating and before or after size preparation. The prepared particles are applied to HGMS apparatus and fractionated according to magnetic susceptibility). This teaching would apply to the limitation of claim 3- passing the magnetic microspheres through a magnetic field prior to the initial separation

stage.(see col. 7, lines 55-62). Coating of the polymeric material around the microcrystals is the same as imbedding and immobilizing microcrystals on the surface of or within an organic polymeric material or glass because the polymeric coating also attaches to the magnetic crystals through the reactive group.

New Ground(s) of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14, line 1 is indefinite for failing to recite ***what*** "are immobilized..."

Claim 15 is indefinite for reciting "forming said magnetic microspheres..." because claim 1 does not recite any step of forming the magnetic microspheres. Such step (forming...) is also confusing because claim 14 does not recite the sequential order of that step with respect to the order of the steps in claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miltenyi (US 5,543,289) in view of McDevitt et al. (US 6,649,403).

Miltenyi has been discussed above.

However, Miltenyi fails to teach the magnetic particles are selected from the group consisting of iron-cobalt, iron-platinum and samarium-cobalt.

McDevitt teaches assay and system for rapid characterization of multi-analyte fluids using magnetic particles comprising of magnetic materials such as samarium-cobalt. (see col. 114, lines 28-46).

It would have been obvious to one of ordinary skills in the art to use the magnetic material such as samarium-cobalt as taught by McDevitt in the method of Miltenyi since samarium-cobalt can be incorporated in colloidal particles. Samarium-cobalt is a rare-earth magnetic material which exhibits maximum magnetic property.

Response to Arguments

Applicant's arguments filed on March 30, 2005 have been fully considered but they are not persuasive.

Regarding the rejection under 102(b) by Miltenyi, Applicants submit that Miltenyi does not teach all the limitations of amended claim 1. Claim 1 has been amended to include the limitation that the magnetic microspheres each include a plurality of magnetic particles that are either coated, embedded in the magnetic microspheres or immobilized on a surface of or within the magnetic microspheres. Miltenyi does not teach microspheres comprising a plurality of magnetic particles.

The magnetic particles of Miltenyi are collections of iron oxide microcrystals. These iron oxide microcrystals are coated with a polysaccharide such as dextran which can be added after the colloidal oxide particles are formed. (see col. 7, lines 9-17, and 49-51). The iron oxide microcrystals are considered magnetic particles and are coated with a polysaccharide to form a magnetic microsphere. Therefore, Miltenyi still applies to the amended claims.

Regarding the correct order of claims being examined now, the number of the rejected claims are different than those in the previous office action. However, the rejected subject matters are the same.

Regarding claim 8, which was claim 7 in the "elected list" and has been indicated allowable in the previous office action, since new relevant art has been found for the limitation of claim 8, it is no longer allowable.

Allowable Subject Matter

Claims 15 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

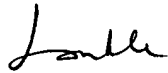
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
June 9, 2005


LONG V. LE
SUPERVISORY PATENT EXAMINER
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06/15/05